

MODIFIED VERSION OF THE SNIF FOR APPLICATION **C/NL/04/02** SUBMITTED BY FLORIGENE
CONCERNING THE CARNATION WITH MODIFIED COLOUR.

THIS NEW SNIF IS REVISED AS THE APPLICANT HAS WITHDRAWN ONE GM LINE FROM THE
APPLICATION AND HAS ADDED A CONTACT PERSON IN UK.

SECTION E

SNIF PART 2: Summary information format for products containing genetically modified higher plants (GMHPs)

GENERAL INFORMATION

E.1. Details of notification

(a)	Member State of notification: The Netherlands
(b)	Notification number: C/NL/04/02
(c)	Name of the product (commercial and other names): <i>Florigene Moonlite™</i> (123.2.38)
(d)	Date of acknowledgement of notification: 9 September 2004

E.2. Notifier

(a)	Name of notifier: Florigene Limited (Australia)
(b)	Address of notifier: 16 Gipps Street, Collingwood, VIC 3066, Australia
(c)	Is the notifier domestic manufacturer: No Importer: Yes
(d)	In case of an import the name and address of the manufacturer shall be given: Florigene Limited, 16 Gipps Street, Collingwood, VIC 3066, Australia
(e)	Name and full address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor; Ms. Shuna Mitchell Suntory Ltd. Buchanan House 3 St. James's Square, London SW1Y4JU, U.K. Phone 44-20-7839-9370 Fax 44-20-7839-9379 e-mail s.mitchell@suntory-uk.co.uk

E.3. General description of the product

<p>(a) Name of recipient or parental plant and the intended function of the genetic modification: Recipient plant is <i>Dianthus caryophyllus</i> L. (UK carnation, NL anjer, ESP clavel). The product line of the present application consists of a variety in which the flowers have a modified flower colour as the result of genes enabling the biosynthesis of delphinidin pigment in the flowers. The flowers also carry an herbicide resistance gene to facilitate selection <i>in vitro</i>.</p>																
<p>(b) Any specific form in which the product must not be placed on the market (seeds, cut-flower, vegetative parts, etc.) as a proposed condition of the authorization applied for: None</p>																
<p>(c) Intended use of the product and types of users: The flower product will be sold in the cut flower market in the same way as other carnation flowers. Users include flower importers, flower auctioneers, flower wholesalers, retailers, and florists. Flowers will ultimately be sold to the general public.</p>																
<p>(d) Any specific instructions and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorization applied for: There are no specific requirements.</p>																
<p>(e) If, applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorization applied for: None</p>																
<p>(f) Any type of environment to which the product is unsuited: None</p>																
<p>(g) Any proposed packaging requirements: No specific packaging will be used for transport or marketing of the cut-flowers. The flowers will be handled according to general practice in handling carnations.</p>																
<p>(h) Any proposed labeling requirements in addition to those required by law: Imported flowers will include a label in each box stating; "These flowers are genetically modified to alter the flower colour and are only produced for use as an ornamental product."</p>																
<p>(i) Estimated potential demand: At this stage this is difficult to estimate as the popularity of flower colour is highly sensitive to changes in consumer's taste. Currently, the estimated annual consumption in Europe is expected to be between 2.5 and 25 million flower stems.</p>																
<p>(j) Unique identification codes(s) of the GMO(s):</p> <table border="1"> <thead> <tr> <th data-bbox="204 1778 453 1816">Identifier number</th> <th data-bbox="564 1778 772 1816">Trade name</th> <th data-bbox="783 1778 995 1816">Florigene codes</th> <th data-bbox="1070 1778 1171 1816">Unique</th> </tr> </thead> <tbody> <tr> <td data-bbox="204 1832 453 1870"></td> <td data-bbox="564 1832 772 1870">BCH reference</td> <td data-bbox="783 1832 995 1870"></td> <td data-bbox="1070 1832 1171 1870"></td> </tr> <tr> <td data-bbox="204 1886 453 1924"><i>Florigene Moonlite</i>™</td> <td data-bbox="564 1886 772 1924"></td> <td data-bbox="783 1886 995 1924">123.2.38 (also 40644)</td> <td data-bbox="1070 1886 1171 1924">FLO-40644-4</td> </tr> <tr> <td data-bbox="204 1939 453 1977"></td> <td data-bbox="564 1939 772 1977">10066</td> <td data-bbox="783 1939 995 1977"></td> <td data-bbox="1070 1939 1171 1977"></td> </tr> </tbody> </table>	Identifier number	Trade name	Florigene codes	Unique		BCH reference			<i>Florigene Moonlite</i> ™		123.2.38 (also 40644)	FLO-40644-4		10066		
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<i>Florigene Moonlite</i> ™		123.2.38 (also 40644)	FLO-40644-4													
	10066															

E.4. Has the GMHP referred to in this product been notified under Part B of Directive 2001/18/EC and/or Directive 90/220/EEC?

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<p>If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC: The transformation experiments resulting in line <i>Florigene Moonlite</i>TM (123.2.38) were executed by Florigene Europe B.V. in the Netherlands. The plants were propagated and planted in trials in the Netherlands, at the premises of Florigene Europe B.V. under permit number BGGO 95/12-2 (SNIF B/NL/95-012/02).</p> <p><i>Florigene Moondust</i>TM, produced by use of the same transformation vector has marketing approval in the EU (C/NL/96/14-11).</p>	

E.5 (a) Is the product being simultaneously notified to another Member State?

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<p>(i) If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC:</p>	

E.5 (b) Has the product been notified in a third country either previously or simultaneously?

Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
<p>(i) If yes, specify: <i>Florigene Moonlite</i>TM (123.2.38) has previous approval for production in Ecuador, Colombia, Japan and Australia and may be imported into Canada, the USA and Japan.</p>	

E.6. Has the same GMHP been previously notified for marketing in the Community?

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<p>(i) If yes, give notification number and Member State:</p>	

E.7. Measures suggested by the notifier to take in case of unintended release or misuse as well as measures for disposal and treatment

None.

NATURE OF THE GMHP CONTAINED IN THE PRODUCT INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

E.8. Complete name

(a) Family name:	Caryophyllaceae
(b) Genus:	<i>Dianthus</i>
(c) Species:	<i>caryophyllus</i>
(d) Subspecies:	Not applicable
(e) Cultivar/breeding line:	Recipient variety 123
(f) Common name:	Carnation

E.9 (a) Information concerning reproduction

(i) Mode(s) of reproduction:	The cultivated carnation is vegetatively propagated and to produce plants for cut flower production. Cuttings are taken from vegetative 'mother plants' which are continually pruned to produce a high number of vegetative cuttings from axillary buds. These cuttings are rooted in conditions of high humidity, after treatment with rooting powder. Rooted plants may be planted in soil or grown hydroponically, and are kept for 1-2 years. Flowers are produced in flushes, beginning 3-5 months after rooted cuttings are planted. Picking of all flowers is essential and flowers must be harvested in tight bud (or closed bud for spray types) for distribution and marketing. Carnation is not reproduced by seed, and seed cannot form during cultivation. Carnation pollen can only be dispersed by lepidopteran insects such as moths. Pollen is not wind dispersed.
(ii) Specific factors affecting reproduction, if any:	Imported cut flowers have no capacity for gene dispersal by seed formation or pollen dispersal.
(iii) Generation time:	Cultivated carnation is grown for 1 to 2 years.

E.9 (b) Sexual compatibility with other cultivated or wild plant species

Carnations are double-flowered cultivars and in the general trade and botanical and horticultural literature carnation cultivars are considered to belong to the species *Dianthus caryophyllus*. The common name for *Dianthus caryophyllus* is carnation. However, the exact taxonomic and breeding history of carnation is not known and it is almost certain that carnation is a hybrid involving two or more *Dianthus* species, one of which is likely to be *Dianthus caryophyllus*.

Whilst there are wild *Dianthus* species in Europe, there is no compatibility between these plants and imported carnation flowers. There is no potential for hybridization. No report exists of spontaneous hybridization between the cultivated carnation in Europe and either wild *Dianthus* types or species of other genera.

E.10. Survivability

(a) **Ability to form structures for survival or dormancy:** The survival structures carnation can produce are seeds and pollen, though it is impossible for imported carnation flowers to form seed.

(b) **Specific factors affecting survivability, if any:** Imported carnation flowers will not survive more than 3 weeks in the hands of the consumer. During this time seed set is impossible. Discarded carnation flowers have no vegetative propagation ability.

E.11. Dissemination

(a) **Ways and extent of dissemination:** Genetic material from cultivated carnation plants could theoretically be disseminated through seed or insect pollination or vegetative propagation. None of these avenues are realistic avenues for gene dispersal in the case of the carnation flowers imported into Europe.

(b) **Specific factors affecting dissemination, if any:** Not applicable.

E.12. Geographical distribution of the plant

The carnation is a cultivated plant and is not found in the wild, but is grown worldwide. In Europe, main production countries are Italy, Spain and the Netherlands. Carnation flowers are imported into the EU from Africa, South America and the middle East. Wild *Dianthus caryophyllus* is very rare and can only be found in specific coastal regions of Corsica, Sardinia, France and Italy.

E.13. In the case of plant species not normally grown in the Member States(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts

Not applicable. Carnation flowers are routinely imported into the EU from Africa, South America and the middle East, and are also widely grown in Europe. Several billion carnation flowers are distributed within the EU per annum.

E.14. Potentially significant interactions of the plant with other organisms in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms

The products are imported cut flowers, and the receiving environment is the commercial environment of airports, warehouses, trucks and shops, and the home. Discarded flowers will be dead, or soon die, have no ability to survive after use and will not enter human or animal food chains.

Carnation has been used safely by humans for ornamental purposes for centuries. The modification in the GMHP (production of delphinidin) is novel for carnation, but there are many flowers and other ornamental species that produce delphinidin. Delphinidin is also present in many common foods.

Direct tests of potential toxicity indicate no potential for harm to plant, animal or human health.

There is now a long history of safe use of the products. Carnation is not reported to be a poisonous plant, or to cause allergic reactions, and there is no evidence that the transgenic line has, or could, cause an adverse reaction.

E.15. Phenotypic and genetic traits

The product consists of imported flowers from carnation plants that have a modified flower colour and are herbicide resistant.

Phenotype

Flower colour is generally the result of the relative concentration and type of two pigment types - carotenoids and flavonoids. Carotenoids are responsible for yellow through orange colours however most plants do not contain carotenoid pigments. Anthocyanins are flavonoid based coloured pigments. There are three groups of anthocyanins, the delphinidins that generally produce blue flower colour, cyanidins that produce red or pink flower colour, and pelargonidins that produce orange or brick red flower colour. Non-genetically modified carnations lack the part of the anthocyanin biosynthetic pathway that is responsible for the production of delphinidin, as they lack a gene encoding the enzyme

flavonoid 3'5' hydroxylase that converts dihydrokaempferol (DHK) to dihydroquercetin (DHQ) and then to dihydromyricetin (DHM). In the genetically modified carnations commercialized by Florigene a gene encoding DFR has also been introduced as the particular non-genetically modified starting material used lacked both F3'H and DFR activity. The enzyme DFR can use either DHK, DHQ or DHM as substrate. Delphinidin is thus produced as a result of the combined expression of the introduced genes DFR and F3'5'H together with endogenous genes in the anthocyanin biosynthetic pathway. The production of delphinidin results in a change in flower colour.

Genotype

Three genes have been transferred;

- the **petunia DFR gene**, coding for dihydroflavonol 4-reductase (DFR), derived from *Petunia X hybrida*. The petunia DFR enzyme is only capable of using dihydroquercetin and dihydromyricetin as substrate, not dihydrokaempferol. This ensures that most or all of the anthocyanidin produced is delphinidin. A constitutive promoter drives the petunia *DFR-A* cDNA derived gene.
- the **petunia F3'5'H gene (*Hfl*)**, coding for flavonoid 3' 5' hydroxylase (F3'5'H), derived from *Petunia X hybrida*. F3'5'H acts by converting the dihydroflavonols dihydrokaempferol and/or dihydroquercetin into the dihydroflavonol dihydromyricetin. The cDNA for F3'5'H encodes the enzyme F3'5'H allowing transgenic plants normally lacking this enzyme to produce violet or blue delphinidin derived pigments.
- **ALS gene (*SuRB*)**, coding for a mutant acetolactate synthase protein (ALS), derived from *Nicotiana tabacum*. Expression of the mutation confers resistance to sulfonylurea herbicides.

INFORMATION RELATING TO THE GENETIC MODIFICATION

E.16. Description of the methods used for the genetic modification

Genetic material was inserted into carnation by *Agrobacterium*-mediated transformation using the disarmed *Agrobacterium tumefaciens* strain AGL0 carrying the transformation vector pCGP1470, developed by Florigene Limited, Collingwood, Australia.

E.17. Nature and source of the vector used

The transformation vector pCGP1470, developed by Florigene Limited, Collingwood, Australia.

E.18. Size, source of the vector used

Position (nt)	Genetic Element	Origin	Function
25092-563 (25587)	LB	Ti plasmid <i>A. tumefaciens</i>, octopine strain	Defines junction between T-DNA and plant genomic or vector DNA. Utilized in transfer of insert to plant cell and integration into genome.
564-571	polylinker	pBluescript/pUC, <i>E. coli</i>	Residual sequences from vectors used in assembling transformation vector.
572-770	35S promoter	Cauliflower Mosaic Virus (CaMV)	Constitutive promoter in plants.
771-831	Cab 5'utr	<i>Petunia X hybrida</i>	Chlorophyll a/b binding protein 5' untranslated region (utr) from cDNA.
832- (2826) 4596	SuRB (ALS)	Tobacco, <i>N. tabacum</i>	Encodes acetolactate synthase resistant to chlorsulfuron. Gene with own terminator (no promoter).
4597-4844	polylinker	pBluescript/pUC, <i>E. coli</i>	Residual sequences from vectors used in assembling transformation vector.
4845-6010	CHS promoter	<i>Antirrhinum majus</i>	Flavonoid pathway promoter from a gene encoding chalcone synthase.
6011- (6053-7573) -7603	F3'5'H cDNA	<i>Petunia X hybrida</i>	Encodes flavonoid 3'5'-hydroxylase, a key enzyme in the anthocyanin biosynthesis pathway.
7604-8410	'D8' terminator	<i>Petunia X hybrida</i>	Terminator sequence from petunia 'D8', a gene encoding a phospholipid transfer protein homologue.
8411-8551	polylinker	pBluescript/pUC, <i>E. coli</i>	Residual sequences from vectors used in assembling transformation vector.
8552-9777	Mac promoter	CaMV & <i>A. tumefaciens</i>	A hybrid constitutive promoter in plants (mas promoter & 35S enhancer elements).
9778- (9812-10954) -11106	DFR cDNA	<i>Petunia X hybrida</i>	Encodes dihydroflavonol 4-reductase, a key enzyme in the anthocyanin biosynthesis pathway
11107-11824	Mas terminator	<i>A. tumefaciens</i>	Terminator sequence from <i>A. tumefaciens</i> mannopine synthase (wtpTi).
11825-13672	RB	Ti plasmid <i>A. tumefaciens</i>, octopine strain	Defines junction between T-DNA and plant genomic or vector DNA. Utilised in transfer of insert to plant cell and integration into genome.
13673-13682	polylinker	pBluescript/pUC, <i>E. coli</i>	Residual sequences from vectors used in assembling transformation vector.
13683-21589	pVS1 replicon & pPZP100 seq	<i>Pseudomonas aeruginosa</i>	For replication of transformation vector in <i>A. tumefaciens</i> .
21590-23562	Tet resistance gene complex	<i>Escherichia coli</i>	For selection of bacteria carrying the transformation vector.
23563-25091	Modified pACYC184 replicon	<i>Escherichia coli</i>	For replication of transformation vector in <i>E. coli</i> only.

INFORMATION RELATING TO THE GMHP

E.19 Description of the trait(s) and characteristics, which have been introduced or modified

Flowers of the genetically modified carnation product of this application produce delphinidin whilst carnations which are not modified do not. The production of delphinidins results in a change in flower colour. The flower products of this application are a shade of violet, compared to the white flowers of the line from which the transgenic line was derived.

E.20 Information on the sequences actually inserted/deleted/modified

- (a) **Size and structure of the insert and methods used for its characterization, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP:** The T-DNA is 12,292 base pairs. The size and structure of the inserts have been analyzed by Southern blot analysis and the T-DNA between the left and right borders of pCGP1470 remains in the GMO. Through Southern Blot analysis it has been shown that an amount of DNA outside the T-DNA borders is present in the GMO. No carrier (*Agrobacterium*) remains in the GMHP.
- (b) **In the case of deletion, size and function of the deleted region(s):** Not applicable.
- (c) **Location of the insert in the plant cells (integrated in the chromosome, chloroplast, mitochondrion, or maintained in a non-integrated form) and method for its determination:** The insert is integrated into the plant chromosome.
- (d) **Copy number and genetic stability of the insert:**
Copy number is described as part of the Southern analysis, and is summarised here.

Probe	Estimated Copy Number
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LB	1
SuRB	1
F3'5'H	1
DFR	1-2

RB
3

Florigene Moonlite™ (123.2.38) has been vegetatively propagated since 1998. As of August 2004, this represents approximately 7 generations of mother plants and approximately 150 collections of cuttings from these plants. Since 1999 plants have been in continuous commercial production in Australia, Ecuador and Colombia. Estimated number of flowers produced from our two production facilities in South America to mid August 2004 is approximately 4.3 million flowers. Measured by flower colour, the line is genetically very stable.

- (e) **In case of modification other than insertion or deletion, describe function of the modified genetic material before and after modification as well as direct changes in expression of genes as a result of the modification:** Not applicable.

E.21 Information on the expression of the insert

- (a) **Information on the expression of the insert and methods used for its characterization:**
Expression of the insert has been determined by the presence of delphinidin-type pigments using TLC and HPLC techniques. Flowers of the product contain 0.1 – 0.2 mg delphinidin per gram fresh weight, determined by HPLC.
- (b) **Parts of the plant where the insert is expressed (e.g. roots, stem, pollen, etc):** Flowers of the genetically modified carnation product produce delphinidin whilst carnations which are not modified do not. The production of delphinidin results in a change in flower colour. Transgenic flowers are violet, compared to the white flowers of the control line. Delphinidin production has not been observed in other tissues of the transgenic flowers and plants, such as stems, nodes, leaves and roots. Production of delphinidin is confined to the petals as result of the use of floral specific promoters for some genes and because the biochemical pathway leading to anthocyanin biosynthesis is induced to coincide with flower development.

E.22 Information on how the GMHP differs from the recipient plant in:

- (a) **Mode(s) and/or rate of reproduction:** There no avenue of reproduction from imported cut flowers of either recipient or GMO.

- (b) Dissemination:** There are three theoretical avenues of gene dispersal from an imported carnation flower;
1. Vegetative spread of the imported cut flowers, leading to the formation of wild clonal populations.
 2. Formation and dispersal of seed from the imported cut flower as a result of self fertilization or fertilization with pollen from an external source.
 3. Formation of seed by a recipient plant, fertilized by pollen dispersed from the imported cut flower.
- The probability of gene dispersal from a carnation flower, of recipient or GM origin, is negligible to nil.
- (c) Survivability:** Imported flowers of the GMO have no greater ability to survive than flowers from any other carnation variety, including the recipient.
- (d) Other differences:** The primary difference between *Florigene Moonlite™* (123.2.38) and the recipient plant is in the colour of the flowers, because of the production of delphinidin in the GMO.

E.23 Potential for transfer of genetic material from the GMHP to other organisms

There is an extremely low risk of gene dispersal for imported carnation flowers. The imported flowers from the GMHP have no enhanced ability to transfer genetic material.

E.24 Information on any harmful effects on human health and the environment, arising from the genetic modification

Carnation has been used safely by humans for ornamental purposes for centuries. The modification in the GMHP (production of delphinidin) is novel for carnation, but there are many flowers and other ornamental species that produce delphinidin. Delphinidin is also present in many common foods. Carnation is not reported to be a poisonous plant, or to cause allergic reactions, and there is no evidence that the transgenic line has, or could, cause an adverse reaction. There is now an extensive history of safe use of the products overseas. Carnation is not used as a food but there is a slight possibility that some home consumers may decide to eat flower petals, or garnish foods with flower petals. In the event that this did occur we do not believe the transgenic carnation poses any health risk because the novel products in the GMHP are found naturally in many foods. Open reading frame analysis of introduced regions of DNA reveals that the deduced amino acid sequences of the

transgenic carnation lines in this application appear not to be homologous to any known toxic or allergenic proteins. Direct tests of potential toxicity indicate no potential for harm to plant, animal or human health.

There is no potential for gene dispersal. The settings in which the imported flowers will be used, the relatively small number of flowers imported, their dispersal across Europe, and the short longevity of the flowers are all factors that preclude any direct or indirect effect on the environment.

E.25 Information on the safety of the GMHP to animal health, where the GMHP is intended to be used in animal feedstuffs, if different from that of the recipient/parental organism(s)

Not applicable. The product is not intended to be used as animal feed.

E.26 Mechanism of interaction between the GMHP and target organisms (if applicable), if different from that of the recipient/parental organism(s)

Not applicable. There are no target organisms.

E.27 Potentially significant interactions with non-target organisms, if different from the recipient or parental organism(s)

The flowers from the GMPH are intended to be used for human consumption as an ornamental product, in the same way as other carnation flowers. There are no changes in this interaction as a result of the genetic modification.

E.28 Description of detection and identification techniques for the GMHP, to distinguish it from the recipient or parental organism(s)

The GMHP can be distinguished using DNA based identification methods, such as Southern analysis and

PCR. A PCR based identification technique has also been developed that will allow the product to be distinguished from other transgenic carnation lines.

Flower colour can be used to distinguish the product from the recipient plant, and biochemical tests such as thin layer chromatography may be used to determine that delphinidin is produced. The product, but no non GM carnation variety, is able to produce delphinidin.

INFORMATION ON THE POTENTIAL ENVIRONMENTAL IMPACT FROM THE RELEASE OF THE GMHP

E.29 Potential environmental impact from the release or the placing on the market of GMOs (Annex II, D2 of Directive 2001/18/EC), if different from a similar release or placing on the market of the recipient or parental organism(s)

There is no environmental impact from the placing on the market of the GMO which would be different to that of placing flowers from the recipient plant on the market. Carnation flowers from many varieties, including the recipient, are a commodity in the EU, and several billion non-GM carnation flowers are consumed per annum in the community. There is no evidence the products would have any adverse effects;

1. An analysis of the potential of gene dispersal from carnation flowers imported into the EU shows no potential for gene dispersal as a result of vegetative spread from discarded flowers. The flowers are therefore not invasive and there is no opportunity for the cut flowers to become “weeds”. In any event, carnation is not a weed in Europe and despite hundreds of years of cultivation, and plantings in parks and gardens, it has not become a weed, or escaped from cultivation, anywhere in the world.
2. An analysis of the potential of gene dispersal from carnation flowers imported into the EU shows gene dispersal as a result of seed formation by imported flowers is impossible.

3. An analysis of the potential of gene dispersal from carnation flowers imported into the EU shows no potential for gene dispersal as a result of pollen flow from imported flowers. No hybrid between carnation and any other *Dianthus* species has ever been recorded in the wild.
4. Field trial data and the history of release of several other GM carnation varieties in the world provides evidence that release of transgenic carnation poses no risk to health or the environment, in comparison to the cultivation of non-GMO carnation.
5. There is no evidence that carnation flowers in general, and the transgenic line that is the subject of this application specifically, have any pathogenic, phytotoxic, toxic or allergenic properties.

*Florigene Moonlite*TM(123.2.38) has a history of safe use outside the EU. Recent environmental risk assessments by the Australian and Japanese governments determined the product posed no risk to environment or biodiversity.

The transgenic carnation variety *Florigene Moondust*TM has already been approved for commercial production within the EU (C/NL/96/14-11). This variety was developed with the same transformation vector as *Florigene Moonlite*TM(123.2.38).

E.30 Potential environmental impact of the interaction between the GMHP and target organisms (if applicable), if different from that of the recipient or parental organism(s)

Not applicable. There are no target organisms.

E.31 Possible environmental impact resulting from potential interactions with non-target organisms, if different from that of the recipient or parental organism(s)

- (a) **Effects on biodiversity in the area of cultivation:** Not applicable. The products are cut flowers and will not be cultivated.
- (b) **Effects on biodiversity in other habitats:** Not applicable. The imported cut flowers have no means to become established in any habitat.
- (c) **Effects on pollinators:** Not applicable. Imported cut flowers are very unlikely to come into contact with pollinators in the environment in which they will be used.

(d) Effects on endangered species: Not applicable. The imported cut flowers have no means to become established, and will be consumed in the human household environment in the same way as other carnation flowers.

INFORMATION RELATING TO PREVIOUS RELEASES

E.32 History of previous releases notified under Part B of the Directive 2001/18/EC and under Part B of Directive 90/220/EEC by the same notifier

(a) Notification number: The variety *Florigene Moonlite*TM (123.2.38) has not been notified. However, similar products have been approved under Part B of directive 90/220/EEC and two varieties of these approved GM carnation are already imported into the EU;

Trade name

Transformation vector

OECD ID No. (Unique Identifier)

EU approval & registration No.

*Florigene Moondust*TM

pCGP1470

FLO-07442-4

C/NL/96/14-11

*Florigene Moonshadow*TM

pCGP1991

FLO-11363-1

- (b) Conclusions of post-release monitoring:** Production sites overseas have been monitored for escapes, and none have been found. There have been no reports from customers in the EU relating to harmful effects on human health.
- (c) Results of the release in respect to any risk to human health and the environment (submitted to the competent authority according to Article of Directive 2001/18/EC):** No human health or environmental risks were observed.

E.33 History of previous releases carried out inside or outside the Community by the same notifier

- (a) Inside the community:** The transformation experiments resulting in lines *Florigene Moonlite™* (123.2.38) were executed by Florigene Europe B.V. in the Netherlands. In 1997 the first plants flowered under a contained use permit. Trials were carried out in the summers of 1999 and 2000 under permit number BGGO 95/12-02.

- (b) Outside the community:**

USA

Florigene Moonlite™ (123.2.38) has been sold across the USA since November 2000.

Canada

Flowers from line *Florigene Moonlite™* (123.2.38) have been imported into Canada in very small numbers since April 2001.

Colombia

A resolution permitting commercial release was issued in May 2000. Production of *Florigene Moonlite™* (123.2.38) began in early 2000 and first flowers were exported from November 2000.

Australia

The Office of the Gene Technology Regulator (OGTR) has granted Florigene a licence for commercial use of four colour-modified transgenic carnation varieties, including *Florigene Moonlite™* (123.2.38).

Japan

Marketing approval for *Florigene Moonlite™* (123.2.38) was granted by MAFF in December 2000 (approval number 12 Nokai No. 2221). Flowers have been sent to Japan from Ecuador

and Colombia since March 2001.

INFORMATION RELATING TO THE MONITORING PLAN- IDENTIFIED TRAITS, CHARACTERISTICS AND UNCERTAINTIES RELATED TO THE GMO OR ITS INTERACTION WITH THE ENVIRONMENTAL THAT SHOULD BE ADDRESSED IN THE POST –COMMERCIALIZATION MONITORING PLAN

E.34 Information relating to the monitoring plan- identified traits, characteristics and uncertainties related to the GMO or its interaction with the environmental that should be addressed in the post – commercialization monitoring plan

Transgenic carnation, and specifically the carnation line that is the subject of this proposal, now has a history of safe use. There is also sufficient history of use to support the fact that the biology of the crop precludes gene dispersal and dissemination from transgenic carnation at either production locations or after import of flowers.

- In trials and a period of commercial production in Europe, no observations were made to suggest that GMHP behaved any differently to non genetically modified carnation.
- Transgenic carnation flowers have been imported into the EU on a virtually weekly basis for the past 18 months. We have received no reports from the users of these flowers to suggest any features or characteristics that would require further monitoring.
- Several hundred thousand plants of *Florigene Moonlite™* (123.2.38) have been grown in South America since 2000, and several million flowers produced. Surveys of the production sites have found no evidence of dissemination from outside of the cultivation area and there have been no adverse effect reports from any of the workers handling the plants or flowers.
- Several million flowers of *Florigene Moonlite™* (123.2.38) have been exported to the USA and Japan with no reports of adverse effects on distributors or end users.
- There is experience of growing and selling two similar transgenic carnation varieties within the EU, without any reports of adverse effects.

The environmental risk assessment indicates no risks associated with the import of the GMHP and that issues associated with imports are the same as non GM carnation flowers. As the flowers will not

be grown in the EU, there is no requirement for monitoring of production locations within the EU. Information collected will be from general surveillance, rather than collection of specific data, or tracing products to end use.